

§ 158.1

158.2220 Product performance.
158.2230 Toxicology.
158.2240 Nontarget organisms.
158.2250 Nontarget plant protection.
158.2260 Applicator exposure.
158.2270 Post-application exposure.
158.2280 Environmental fate.
158.2290 Residue chemistry.

Subpart X–Z [Reserved]

158.2300–158.2500 [Reserved]

AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 346a.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

Subpart A—General Provisions

§ 158.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to specify the kinds of data and information EPA requires in order to make regulatory judgments under FIFRA secs. 3, 4, and 5 about the risks and benefits of pesticide products. Further, this part specifies the data and information needed to determine the safety of pesticide chemical residues under FFDCA sec. 408.

(b) *Scope.* (1) This part describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process, e.g., as used in the registration review program; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

(2) This part establishes general policies and procedures associated with the submission of data in support of a pesticide regulatory action.

(3) This part does not include study protocols, methodology, or standards for conducting or reporting test results; nor does this part describe how the Agency uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data.

(c) *Scope of individual subparts.* (1) *Conventional pesticides.* Subparts A, B, C, D, F, G, K, L, N, and O apply to conventional pesticides.

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(2) *Biochemical pesticides.* Subparts A, B and U apply to biochemical pesticides.

(3) *Microbial pesticides.* Subparts A, B and V apply to microbial pesticides.

(4) *Antimicrobial pesticides.* [Reserved]

EFFECTIVE DATE NOTE: At 78 FR 26978, May 8, 2013, § 158.1 was amended by revising paragraph (c)(4), effective July 8, 2013. For the convenience of the user, the revised text is set forth as follows:

§ 158.1 Purpose and scope.

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(c) * * *

(4) *Antimicrobial pesticides.* Subparts A, B, C, D, and W of this part apply to antimicrobial pesticides.

§ 158.3 Definitions.

All terms defined in sec. 2 of the Federal Insecticide, Fungicide, and Rodenticide Act apply to this part and are used with the meaning given in the Act. Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part. Individual subparts may contain definitions that pertain solely to that subpart. The following additional terms apply to this part:

Applicant means any person or entity, including for the purposes of this part a registrant, who submits, or is required to submit, to the Agency any application, petition, or submission intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following:

(1) An application for registration or amended registration of a pesticide product under FIFRA sec. 3 or 24.

(2) A submission of data required in conjunction with reregistration of a currently registered product under FIFRA sec. 4.

(3) An application for an experimental use permit under FIFRA sec. 5.

(4) A submission of data in response to a notice issued by EPA under FIFRA sec. 3(c)(2)(B).

(5) A petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA sec. 408.